# PATENT COOPERATION TREATY

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l.	AUG 2005
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### INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference			
Cavd₁01	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)		
International application No.	International filing date (day/mon	th/year)	Priority Date (day/month/year)
PCT/IN 2004/000052	4 March 2004 (04.03.20)	04)	20 June 2003 (20.06.2003)
International Patent Classification (IPC) or nat	ional classification and IPC	<del></del>	
IPC <sup>7</sup> : C07D			
Applicant	· · · · · · · · · · · · · · · · · · ·		
SUN PHARMACEUTICAL INDUS	TRIES LIMITED	•	
<ol> <li>This international preliminary examinated and is transmitted to the applicant</li> </ol>	mination report has been prepar according to Article 36.	ed by this In	ternational Preliminary Examination Authority
2. This REPORT consists of a total o	f <u>3</u> sheets, including this	cover sheet.	
This report is also accompa	nied by ANNEXES, i.e., sheets	of the descri	iption, claims and/or drawings which have been
70.16 and Section 607 of th	or this report and/or sheets cont e Administrative Instructions u	taining rectifinder the PCT	ications made before this Authority (see Rule ).
These annexes consist of a total of	sheets.		
3. This report contains indications rela	ating to the following items:	<del></del>	
1. Basis of the opin	ion		
II. Priority			
III. Non-establishmen	nt of opinion with regard to nov	elty, inventiv	ve step and industrial applicability
IV. Lack of unity of i	invention		
V. Reasoned stateme	ent under Rule 66.2(a)(ii) with a planations supporting such state	regard to nov ment	elty, inventive step or industrial applicability;
VI. Certain documen	ts cited		
VII. Certain defects in	the international application		
VIII. Certain observation	ons on the international applica	tion	
Date of submission of the demand	Date	of completion	n of this report
28.12.2004		15	July 2005 (15.07.2005)
Name and mailing address of the IPEA/A	T Autho	orized officer	
Austrian Patent Office			
Dresdner Straße 87	}		SLABY S.
A-1200 Vienna			50.10.175.15
Facsimile No. 1/53424/200 Form PCT/IPEA/409 (cover sheet) (July 1		hone No. 1/:	53424/348

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/IN 2004/000052

I.		Basis of the report	PC1/IN 2004/000052
1.	Wi	th regard to the elements of the international application:*	
	$\boxtimes$	the international application as originally filed	
	П	the description:	
1	_	pages, as originally filed	
1		pages, filed with the demand	
ļ		pages, filed with the letter of	
		the claims:	
		pages, as originally filed	
1		pages, as amended (together with any statement) under A it I are	
1		pages, filed with the demand pages, filed with the letter of	
l	$\Box$		
	Ш	the drawings:	
		pages, as originally filed pages, filed with the demand	
		pages, filed with the letter of	
		the sequence listing part of the description:	
		pages, as originally filed	
		pages, filed with the demand	
		pages, filed with the letter of	
2.	With	regard to the language, all the elements marked above were available or furning the international application was filed, unless otherwise indicated under this	shada at a sa
	Thes	h the international application was filed, unless otherwise indicated under this is elements were available or furnished to this had been supported to the control of the c	tem.
1		or lumished to this Authority in the following language	ige which in
	_	the language of a translation furnished for the purposes of international search	(under Rule 23 1/b))
į	Ш	the language of publication of the international application (under Rule 48.3(b)	0
(		the language of the translation furnished for the purposes of international prelimer 55.3).	ninary examination (under Rule 55.2 and/
3. Y	With orelin	regard to any nucleotide and/or amino acid sequence disclosed in the interna ninary examination was carried out on the basis of the sequence listing:	tional application, the international
L	' '	contained in the international application in printed form.	
	_  :	iled together with the international application in computer readable form.	
L	_  1	urnished subsequently to this Authority in written form.	
L	_] 1 _	urnished subsequently to this Authority in computer readable form.	
L	ii 	The statement that the subsequently furnished written sequence listing does not ternational application as filed has been furnished.	go beyond the disclosure in the
Ĺ	] 1 b	he statement that the information recorded in computer readable form is identi een furnished.	cal to the written sequence listing has
	T	he amendments have resulted in the cancellation of:	
		the description, pages	
		the claims, Nos.	
		the drawings, sheets/fig	
—E	]-Th b	s report has been established as if (some of) the amendments had not been made eyond the disclosure as filed, as indicated in the Supplemental Roy (Puls 70.20	le, since they have been considered to an
in th	ucen is rej 7).	nent sheets which have been furnished to the receiving Office in response to an port as ,,originally filed" and are not annexed to this report since they do not c	invitation under Article 14 are referred to
Ally	гери	cement sheet containing such amondments	
rm P	CT/I	PEA/409 (Box I) (July 1998))	d annexed to this report.

#### INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/IN 2004/000052

Inventive step (IS)  Claims — NO  Industrial applicability (IA)  Claims 1-12  Telams — NO  Industrial applicability (IA)  Claims 1-12  The following documents were cited in the search report and considered for the examination of the present application:  D1 EP 918055 A1  D2 US 4503067 A  The numbering will be adhered to in the rest of the procedure.  The present application relates to a process for the preparation of carvedilol in two steps reacting the compounds of formula 2 and 5 to form an intermediate compound of formula 6 and hydrogenating the intermediate compound of formula 6 to form carvedilol (according to claims 1- 6 and 10) and a process for the preparation of carvedilol hydrogenating the compound of formula 6 to form carvedilol (according to claims 7-9 and 11-12).  Since none of the cited documents D1-D2 discloses all essential and characteristic features of the present claims 1-12, the subject matter of the present application is regarded to meet the requirement of novelty.  The documents D1 and D2 describe the preparation of carvedilol similar to those of the present case, but the special conditions of the process of the present claims are not suggested. Therefore inventive step is acknowledged.		1	with regard to novelty, inventive step or industrial applicabi ich statement	
Inventive step (IS)  Claims — NO  Industrial applicability (IA)  Claims — NO  Industrial applicability (IA)  Claims — NO  Citations and explanations (Rule 70.7)  The following documents were cited in the search report and considered for the examination of the present application:  D1 EP 918055 A1  D2 US 4503067 A  The numbering will be adhered to in the rest of the procedure.  The present application relates to a process for the preparation of carvedilol in two steps reacting the compounds of formula 2 and 5 to form an intermediate compound of formula 6 and hydrogenating the intermediate compound of formula 6 to form carvedilol (according to claims 1- 6 and 10) and a process for the preparation of carvedilol hydrogenating the compound of formula 6 to form carvedilol (according to claims 7-9 and 11-12).  Since none of the cited documents D1-D2 discloses all essential and characteristic features of the present claims 1-12, the subject matter of the present application is regarded to meet the requirement of novelty.  The documents D1 and D2 describe the preparation of carvedilol similar to those of the present case, but the special conditions of the process of the present claims are not suggested. Therefore inventive step is acknowledged.	Novelty (N)			
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Industrial applicability (IA) Claims 1-12  Claims	inventive step (18)	Claims	1-12	YES
Claims		Claims		NO
Claims	Industrial applicability (IA)	Claims	1-12	T.T.O
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	intermediate compound of and a process for the preparation carvedilol (according Since none of the cited features of the present	ation of to clai docur claims	f carvedilol hydrogenating the compound of ms 7-9 and 11-12). nents D1-D2 discloses all essential and 1-12, the subject matter of the present	f formula 6 to
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